INTRODUCTION

The Health Care Access and Cost Commission ("HCACC" or "Commission") was created by the Maryland General Assembly in 1993 to carryout a number of diverse health care initiatives, including reform of the small employer health insurance market (defined as employers with two (2) to fifty (50) eligible employees and later expanded to include self-employed individuals). The Commission was charged with developing a standard health insurance product to be offered by all carriers without medical underwriting and with provisions for guaranteed issue and renewal. The affordability of the benefit plan must fall between a statutory floor and a ceiling. The actuarial value benefit plan must be at least equal to benefits required to be offered in a federally qualified HMO and the cost of the average premium cannot exceed 12% of Maryland's average annual wage. In order to stay within the 12% cap, the plan is exempt from state mandated benefits. The HCACC's comprehensive standard health benefit plan (CSHBP) is the only product carriers may offer to small employers. In addition to the benefits, copayments and deductibles are fixed for the six systems for delivering the benefits (HMO, POS, PPO, indemnity, triple-option POS, PPO/MSA). The richness of the benefit plan may be enhanced by riders but cannot be reduced. The plan, which has been in effect since July 1, 1994, covers about one-half million lives.

Each year, the HCACC conducts a financial survey of carriers to determine whether the average premium of the plan is within the 12% affordability cap. If the cost is within the cap, the Commission may consider adding benefits. If the average premium exceeds the cap, benefits must be removed or cost-sharing arrangements altered. In its review of the benefit plan, the Commission considers legislative actions requiring mandated benefits in other markets and issues raised by interested parties (i.e., consumers, employers, payers) who are stakeholders in the process. The Commission holds at least one public meeting per year to obtain comments on the adequacy of existing benefits in the plan (one objective has been to maintain a plan that is comparable to the benefits of large group plans). During these benefit considerations, the Commission is very reluctant to add benefits which could significantly increase the average cost of the plan in an effort to keep the average cost well below the "cap" (historically, the average cost of the plan has been less than 90% of the cap). Some of the more significant changes to the benefit plan over the past three years include: adding a 48-hour maternity coverage; increasing inpatient mental health coverage from 25 days to 60 days, and increasing out-of-pocket costs in the indemnity and PPO delivery systems.

THE ISSUE

Background

During the last several years, the increase in the expenditures for prescription drugs has been the subject of discussion, on both a national and local level. Although expenditures for prescription drugs are estimated at only 7% of the total medical expenditures, there have been double-digit increases in price for several years and projections for the future

indicate this trend will continue. Data from the Employee Benefits Research Institute (EBRI) indicate prescription drug expenditures accelerated to 14.1% in 1997. In contrast, total national expenditures, hospital service expenditures and physician expenditures decreased their growth rate to less than 5%. Private insurance payments for pharmaceuticals increased 17.7% in 1997 (EBRI, April 1, 1999). Research suggests that the volume, mix and availability of prescriptions are the major contributing factors to the double-digit growth. A representative of PCS, a pharmacy benefit management group, indicated environmental factors (growth of the elderly population), pharmacy marketing, and product development are key spending drivers (Steven Urbanski, Jr., PCS presentation to PDAC, 4/20/99). However, there is also a body of research that suggests that while the cost of prescription drugs, as a portion of the health care dollar, may be rising, this added cost is offset by the use of drugs to control conditions that could require more expensive procedures or hospitalizations if left untreated. (Marjorie Powell, PhRMA presentation to PDAC, 5/18/99).

Using a drug formulary is one method of containing drug costs that is becoming increasingly more prevalent in the large group market. Effective October 1, 1999, a formulary is defined in Maryland law as "a list of prescription drugs or devices that are covered by an entity" (i.e., insurer or HMO) [Insurance Article §15-830(3)]. Other methods of cost containment being employed by insurers or HMOs include limiting the dollar coverage of the prescription drug benefits, excluding certain classes of drugs from coverage, requiring specific approval prior to dispensing particular classes of drugs and mandatory policies for generic substitution (See Exhibit A). Of all of these methods, only a generic substitution policy is currently in place in the small group market. Generic substitution means that a multi-source prescription drug approved by the Food and Drug Administration may be substituted for the original brand name drug of the same chemical composition.

Although the law governing the small group insurance market is silent on this issue, the use of a formulary is implicitly prohibited in the small group market because it would be considered to reduce access to the pharmaceutical benefit thus creating a negative rider. The discretionary use of a formulary would allow some carriers to restrict the use of prescription drugs making the benefit less than that offered by others. Benefits offered in the CSHBP must be standard.

For several years, carriers have suggested at the public hearings on proposed changes to the CSHBP that carriers be allowed to use their own drug formularies, applied in other markets, to begin to manage prescription drug costs by giving enrollees or the insureds an incentive to choose the least expensive drug. At the November 1998 HCACC meeting, the Commission concluded that a work group of interested parties should be formed to address whether "standards" could be developed to permit the use of different plan formularies in the CSHBP. The standards would have to assure uniformity in the structuring of the benefit while permitting flexibility in the choice of specific drugs. The Commission also charged the work group with considering other means to contain pharmaceutical costs and their associated appropriate consumer protections. It should be noted that the work group was charged with providing advice on what standards could be

required and not with whether a formulary structure should be implemented. The decision to implement the formulary requirement in the CSHBP resides with the Commission. This paper summarizes the work group's activity and recommendations by carriers to the Commission.

PDAC Activities

In January 1999, the Commission appointed a fifteen-member Prescription Drug Advisory Committee (PDAC). The group chaired by the Commission's Executive Director, John Colmers, was comprised of representatives from insurance carriers, HMOs, pharmaceutical manufacturers, Maryland Insurance Administration (MIA) the Maryland Pharmacy Association, MedChi, the state Medicaid program, and the Department of Budget Management which manages the prescription drug benefit for state employees (See Exhibit B). The PDAC met five times over the course of four months. The group heard a presentation from PCS, a pharmacy benefit manager, on trends in prescription drug use and methods being used by carriers to contain costs. The PDAC also heard from PhRMA (Pharmaceutical Research and Manufacturers of America) on the trade-offs between increased prescription drug costs and use of other more expensive benefits such as the use of hospital beds or emergency room services (See Exhibit C for detailed minutes of PDAC meetings.)

The PDAC considered "open" and "closed" formularies. An "open" formulary means that all drugs to treat a covered service (brand and generic) are available to the insured or enrollee albeit at different levels of copayment. In a "closed" formulary only certain medications approved by the health plan or insurer are included for coverage in the pharmacy benefit. The PDAC concluded that an open formulary structure was most compatible with the "Patients' Bill of Rights" passed in the 1999 session of the Maryland General Assembly. (SB 135). The law provides that an insurer or HMO that provides coverage for prescription drugs or devices must make a non-formulary prescription drug available when the following conditions are met:

a. there is no equivalent prescription drug or device in the formulary;
b. the prescription drug or device in the formulary has been ineffective in treating the disease or condition; or
c. the prescription drug or device in the formulary has caused or is likely to cause an adverse reaction.

In enacting these provisions, the State has essentially "outlawed" a totally closed formulary by guaranteeing access to all prescription drugs or devices if a special need can be demonstrated. The bill ***does not*** prohibit a carrier from charging more for a non-formulary drug than a formulary drug even when no substitute for the non-formulary drug is available.[1]

[1] It should be noted, the PDAC made no recommendation with regard to the use of closed formularies in other group markets.

The PDAC further considered how to construct the formulary in terms of tiers of copayment levels. Both testimony and research indicated the use of three-tiered formularies is growing among insurers, HMOs, and pharmacy benefit managers. A pharmacy benefit manager (PBM) is a group that subcontracts to an insurer or HMO to administer pharmacy benefits. A three-tiered formulary consists of a different "tier" of copayments for generic, brand name formulary and brand name non-formulary drugs. According to the American Journal of Health Plans (3/15/99), one audit of managed care formularies indicated the use of three-tier copayments by 62% of plans. Testimony by a representative of PCS to the PDAC (Steven Urbanski, Jr., PCS, April 20, 1999) and a survey of plans by HCACC staff (Zeke Barbour, Prescription Drug Costs in Maryland's Small Group Market, March 1999), confirmed this trend. Average copayments reported were $6.48 for generic drugs, $12.04 for brand name formulary drugs, and $24.45 for brand name non-formulary drugs (AJHP, 3/15/99). Testimony indicated differences between the 2nd and 3rd tier (for brand name drugs) need to be substantial to motivate consumers. Use of a three-tier structure can reduce costs by 3% to 20% (Steven Urbanski, Jr., PCS Presentation to PDAC, April 20, 1999).

The PDAC reviewed other methods of cost containment such as raising the pharmaceutical deductible or limiting the dollar amount of coverage. However, these alternatives were not acceptable to the group since they could limit access and might actually increase costs by delaying needed treatment.

Other States

The PDAC considered activities in other states to assure consumers are protected when formularies are used.

States' regulation of drug formularies is a relatively recent occurrence. Prior to 1997, as few as nine states had laws or regulations addressing formularies. By April 1999, only thirteen states had not acted to regulate formularies and one of these states, Massachusetts, had a bill under consideration.

Regulations in place are listed below in order of prevalence:

- notification that drug benefit includes a formulary;
- disclosure of either formulary or non-formulary drugs;
- access to non-formulary drugs;
- patient liability for non-formulary drugs;
- formulary content;
- formulary creation and maintenance;
- notification of changes to formulary content; and
- physician protection.

In general, state regulation addresses two primary concerns: enrollee's or insured's ability to discover whether a prescription they or their families are taking will be covered;

and enrollee's or insured's ability to, at a minimum, request coverage of non-formulary drugs if medically necessary. (Zeke Barbour, State Regulation of Drug Formularies, May 1999).

CSHBP PRESCRIPTION BENEFIT

COMAR Regulations

The current uniform cost-sharing arrangements for pharmaceutical benefits are specified in COMAR 31.11.06.05 H. (Exhibit D). The current regulations indicate the following:

1. A covered person shall pay a $150 deductible separate from the other deductibles;
2. After each covered person has paid the $150 deducible, the covered person shall pay the lesser of a $15 copayment for each a generic or sole source (brand name with no generic substitute) prescription or the cost of the prescription;
3. If a health care practitioner prescribes a brand-name drug and the covered person selects the brand-name drug when a generic drug is available, the covered person shall pay the $15 copayment plus the difference between the price of the brand-name and the generic drug; and
4. For contracts renewed on or after July 1, 1998, a covered person shall pay one $30 copayment for up to a 90-day supply of maintenance drugs dispensed in a single dispensing of a prescription.

The CSHBP contains a strong financial incentive to use generic drugs and to avoid brand drugs when generics are available. Sole source drugs are available for the same $15 copayment provisions as for generics. The CSHBP's current benefit does not address therapeutic substitution, the substitution of one brand drug for another less costly drug with a different chemical composition.

Cost and Use of Prescription Drugs

In order to provide the PDAC with information on the cost and use of prescription drugs in the small group market, HCACC staff conducted a survey of major carriers (Zeke Barbour, Prescription Drug Costs in Maryland's Small Group Market, March 1999). The five carriers responding represented about 50% of the market. Data were requested for the years 1996, 1997, and 1998. The survey indicated the following:

1. Use and cost of prescription drugs varies widely;
2. No clear patterns of use or cost differentiate HMO and PPO delivery systems; and
3. About ten drugs and their associated conditions account for about one-fifth of prescription drug costs.

The average number of prescriptions written per year for the HMOs was 7.7 as compared to 6.9 for two PPOs reporting. There were no clear patterns of change between 1997 and

1998 in the average number of prescriptions written or in average allowed charge per member.

The top ten drugs accounting for one-fifth of prescription drug costs were associated with the following conditions: depression and obsessive-compulsive disorders; ulcers and gastoesophageal reflux disease; elevated cholesterol; allergies; migraines; and bacterial infections. This information is consistent with that found in other research (Steven Urbanski, Jr., PCS presentation to PDAC, 4/20/99).

PDAC RECOMMENDATIONS

While HCACC staff research specific to the small group market was unable to document a clear trend toward rising costs or use of prescription drugs, it is difficult to ignore evidence in other markets that prescription drug use or costs are rising faster than other health care costs. Plans representing about 50% of the small group market responded to the HCACC staff survey. Of those responding, it is difficult to discern whether costs reported reflect actual costs or are an artifact of the way benefits are offered or documented. Most carriers offer riders to the pharmacy benefit to lower the deductible or copayments. While riders are supposed to be reported separately to HCACC, it is often difficult to sort out actual premiums from riders. What is documented is that the average cost of the CSHBP in the small group market increased by 6% in 1998, almost double the increase in the average annual wage. This was the largest increase since the onset of small group market reform, (HCACC, Summary of Carrier Experience, June 3, 1999). Increased management of the pharmacy benefit is one method for the Commission to consider to remain within the statutory affordability limit.

The PDAC was charged with recommending to the HCACC how a formulary based pharmacy benefit could be structured to encourage through financial incentives insureds or enrollees to choose less costly drugs. The Commission will decide whether to require use of a formulary. The PDAC recommends the following for managing the pharmacy benefit:

1. **Implement a three-tier open formulary (generic; preferred brand; non-preferred brand) with specified copayments and a mandated generic substitution (effective July 1, 2000).**

Discussion: Implementation of this recommendation would require that HCACC repeal its current regulations with regard to copayments and generic substitution and, instead, adopt a three-tiered structure with specified copayments for each level. The PDAC further recommends continuing the current generic substitution requirement to create an incentive to use generic drugs when available. The current requirement is that the payment for a brand drug when a generic is available equals the copayment plus the difference between the cost of the generic and the cost of the brand drug. As with all benefits in the CSHBP, positive riders could be sold to improve the benefit plan by lowering costs or increasing access. In all cases, the copayment may never exceed the

actual cost to the enrollee of the drug. Also, it should be noted that with this proposed structure, a positive rider could be offered to return the structure to what currently exists in the CSHBP.

An example of how this benefit could be structured is presented below with hypothetical copayments:

3-Tiers	**Generic and Sole Source Drugs**	**Generic is Available for Brand Drugs**
Generic	$15	$15
Preferred	$15	$15, plus the difference in price between generic and preferred
Non-Preferred	$30	$30, plus the difference in price between generic and non-preferred

Note that, in this structure, fixed copayments are required for generic and sole source brand name drugs. If an enrollee or insured chooses a brand over an available generic, there is an ancillary charge.

2. **Evaluate the fiscal impact of a three-tier formulary with several different copayment scenarios on the cost of the CSHBP. The copayment structure selected should reduce or neutralize the rate of increase in the cost of the pharmacy benefit.**

Discussion: In evaluating the copayment scenarios, the actuary should make the following assumptions:

a. Maintain the existing $150 deductible for each covered member;
b. Maintain the existing generic tier as lowest copayment level;
c. Establish a middle tier copayment to create a financial incentive for the enrollee or insured to use items on the carrier's preferred formulary list of brand name drugs;
d. Establish a copayment for non-formulary brand name drugs at a level sufficient to provide a financial incentive to use drugs in the other two tiers;
e. Create a copayment structure that will be established as the "ceiling," maintaining the option in the CSHBP for carriers to sell positive riders to lower the copays;
f. Require that in no case will the copayment exceed the cost of the drug.

3. **Require HCACC to evaluate carrier practices with regard to providing consumers with information on the pharmacy benefit.**

The study shall include determining:

a. insured, enrollee, and provider access to a plan's list of preferred drugs and whether there is advance notice on changes to the formulary;
b. frequency of formulary notification; and
c. comprehensiveness of the list of preferred drugs (inclusion of drug classes).

Discussion: Based on the findings of this study, the HCACC should determine whether disclosure requirements or other consumer protections need to be specified in regulation.

OTHER ISSUES

The PDAC considered and ***did not*** adopt other proposals for containing prescription drug costs. The PDAC concluded the HCACC should not:

1. Separate the pharmacy benefit from other benefits in the small group market.

Discussion: The PDAC confirmed the original position of the HCACC in developing the CSHBP that drug therapy is a critical part of a comprehensive treatment regimen and that employers should not be given the option to exclude it.

2. Adopt limits on the pharmaceutical benefit.

Discussion: Research indicates the number of insureds or enrollees exceeding the limit is so small (around 1%) that discontinuing prescription coverage for those who are the sickest and need it most would result in increased costs in other parts of the plan.

3. Alter deductibles.

Discussion: The PDAC concluded deductibles are currently high enough to discourage unnecessary use. Carriers indicated most insureds or enrollees buy down the deductible to obtain greater access to this benefit.